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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 29/00 — A1

(11) International Publication Number: WO 97/44086

(43) International Publication Date: 27 November 1997 (27.11.97)

(21) International Application Number: PCT/US97/08640

(22) International Filing Date: 21 May 1997 (21.05.97)

(30) Priority Data:
08/653,768 24 May 1996 (24.05.96) US

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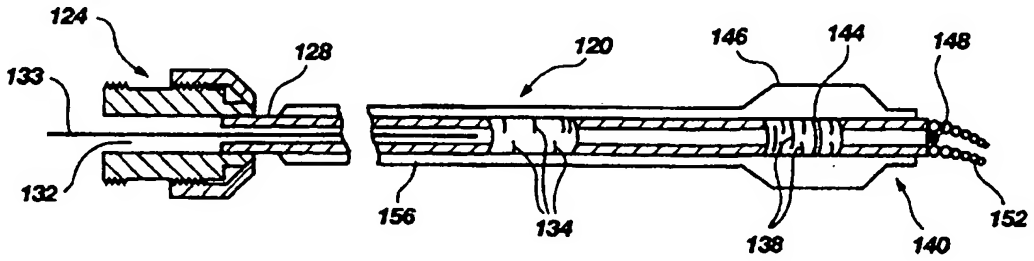
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: FLEXIBLE BALLOON CATHETER/GUIDE WIRE APPARATUS AND METHOD



(57) Abstract

A flexible balloon catheter/guide wire apparatus (120) includes a thin, elongate, hollow tubular body, the exterior surface of which includes a plurality of cuts (138) spaced apart along at least a portion of the length of the body, and some of which extend through to the interior of the tubular body. The cuts extend transversely of the body, and are positioned to give the apparatus flexibility without significantly reducing torsional stiffness. A balloon section (146) is disposed about the tubular body at least near a distal end (140), and about at least some of the cuts which extend through the tubular body to the interior, so that fluid introduced into the hollow at a proximal end (128) of the tubular body will cause the balloon section to inflate outwardly. This structure allows the apparatus to serve both as a guide wire and catheter for threading into a vasculature passageway, and carrying fluid to inflate the balloon section at the target location.

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FLEXIBLE BALLOON CATHETER/GUIDE WIRE APPARATUS AND METHOD

BACKGROUND OF THE INVENTION

This invention relates to catheter systems and more particularly to a flexible balloon catheter/guide wire apparatus and method.

Catheter guide wires have been used for many years to "lead" or "guide" catheters to desired target locations in the human body's vasculature. The typical guide wire is from about 135 centimeters to 195 centimeters in length, and is made from two primary pieces--a stainless steel solid core wire, and a platinum alloy coil spring. The core wire is tapered on the distal end to increase its flexibility. The coil spring is typically soldered to the core wire at its distal end and at a point where the inside diameter of the coil spring matches the outside diameter of the core wire. Platinum is selected for the coil spring because it provides radiopacity for X-ray viewing during navigation of the guide wire in the body, and it is biocompatible. The coil spring also provides softness for the tip of the guide wire to reduce the likelihood of puncture of the anatomy.

Navigation through the anatomy is achieved by viewing the guide wire in the body using X-ray fluoroscopy. The guide wire is inserted into a catheter so the guide wire protrudes out the end, and then the wire and catheter are inserted into a vessel or duct and moved therethrough until the guide wire tip reaches a

desired vessel or duct branch. The proximal end of the guide wire is then rotated or torqued to point the curved tip into the desired branch and then advanced farther. The catheter is advanced over the guide wire to follow or track the wire to the desired location, and provide additional support for the wire. Once the catheter is in place, the guide wire may be withdrawn, depending upon the therapy to be performed. Oftentimes, such as in the case of balloon angioplasty, the guide wire is left in place during the procedure and will be used to exchange catheters.

It is desirable with balloon angioplasty as well as the use of catheters in general to be able to insert the catheter into vasculature passageways which contain numerous turns and tortuous paths to locations far removed from the point of insertion of the catheter. Of course, with numerous turns and tortuous pathways, the internal resistance to movement of the catheter decreases the ability to advance it further which may lead to a failure to access the desired anatomy and thus a failed procedure. A balloon catheter with flexibility and good torque characteristics (torsional stiffness) would, of course, help overcome problems created by the internal resistance.

SUMMARY OF THE INVENTION

It is an object of the invention to provide an improved balloon catheter/guide wire apparatus and method.

It is also an object of the invention to provide such apparatus which exhibits torsional stiffness, bending flexibility, and longitudinal strength.

It is a further object of the invention to provide such apparatus which is simple in design and construction, and allows for selectively varying the bending flexibility of the apparatus along the length thereof.

The above and other objects of the invention are realized in a specific illustrative embodiment of a balloon catheter/guide wire is formed of a thin, elongate, hollow tubular body of material, the exterior surface of which includes a plurality of cuts spaced apart along at least a portion of the length of the body, and some of which extend through to the interior of the tubular body. The cuts extend transversely of the body and are positioned to give the apparatus flexibility without significantly reducing torsional stiffness. A balloon element is disposed about the tubular body near a distal end about at least some cuts which extend through the tubular body walls to the interior, so that fluid introduced into the hollow at a proximal end of the tubular body will cause the balloon element to inflate outwardly. In this manner, the tubular body serves as both a guide wire and catheter for threading into a vasculature passageway and carrying fluid to inflate the balloon element at the target location.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and other objects, features and advantages of the invention will become apparent from a consideration of the following detailed description presented in connection with the accompanying drawings in which:

FIG. 1 is a side, fragmented, partially cross-sectional view of one embodiment of a flexible balloon catheter/guide wire formed with cuts, in accordance with the present invention; and

FIG. 2 is a side, fragmented, partially cross-sectional view of another embodiment of a flexible balloon catheter/guide wire formed with cuts, also in accordance with the present invention.

DETAILED DESCRIPTION

FIG. 1 is a side, fragmented, partially cross-sectional view of a balloon catheter/guide wire 120 made in accordance with the present invention. A pin vise type torquing chuck 124 is shown attached to a proximal end 128 in the usual manner. The chuck 124 also includes an opening, bore, or luer adapter 132 to allow for introduction of inflating fluid into the interior of the tubular catheter/guide wire 120. (The chuck 124 could be positioned farther toward the distal end of the catheter/guide wire 120, separated from the luer adapter 132.)

Insertable in the hollow of the catheter/guide wire 120 is a wire mandrel 133 which may be made radiopaque to X-ray fluoroscopy to enhance visualization or, if magnetic resonance imaging (MRI) were used, the wire mandrel 133 could be made of a material active for MRI detection such as gadolinium or gadolinium compound, gadolinium encapsulated in a sheath, dysprosium, dysprosium compound or dysprosium encapsulated in a sheath. The purpose of such a wire mandrel, of course, would be to enhance visualization of the catheter/guide wire as it is threaded into vasculature or body cavities.

The wire mandrel could also be used to change the curvature of the catheter/guide wire 120 as desired by the user. For example, the catheter/guide wire 120 could be formed with a portion of it curved or angled (such as the distal end) and a straight wire mandrel 133 could then be inserted into the catheter/guide wire to straighten it out and then removed when desired to allow the catheter/guide wire to resume the curved shape. Alternatively, the catheter/guide wire 120 could be formed to be straight and the wire mandrel 133 formed with selected curves so that when the mandrel were inserted into the catheter/guide wire, the mandrel would cause the catheter/guide wire to assume those same curves and when the mandrel were removed, the

catheter/guide wire would again straighten. In this manner, depending upon the initial shape of the wire mandrel 133 and/or the catheter/guide wire 120, the shape of the catheter/guide wire can be controlled to a certain extent while disposed in vasculature or body cavities.

Advantageously, the catheter/guide wire 120 is constructed of nickel titanium alloy and may range in size from about .008 inches to .090 inches in outside diameter, and about .005 inches to .084 inches in inside diameter, and about 175 to 300 cm in length. The catheter/guide wire 120 could also be made of stainless steel, polymers or other flexible materials having suitable strength.

Cuts, slots, gaps or openings 34 and 38 are formed in the catheter/guide wire 120 along the length thereof, either by saw cutting (e.g. diamond grit embedded semiconductor dicing blade), electron discharge machining, laser cutting or etching (for example using the etching process described in U.S. Patent No. 5,106,455) anisotropically to provide for lateral flexibility in the catheter/guide wire. Cuts 134 are generally perpendicular or crosswise to the long dimension of the catheter/guide wire. (Various cut patterns may be used, however.) Cuts 138, on the distal end 140 of the catheter/guide wire, are formed to extend through the catheter/guide wire 120 walls to allow escape of fluid introduced into the hollow at the proximal end. This will be explained more later.

Formed on the distal end 140 of the catheter/guide wire 120 may be a radiopaque or MRI marker or band 144. The band 144 may be gold or platinum alloy (for X-ray fluoroscopy) or gadolinium or dysprosium, or compounds thereof (for MRI), and may be formed on the distal end 140 by deposition, wrapping or use of the shape memory alloy (NiTi) effect to "lock" the band around the end. The marker 144 is centered inside an expandable balloon

146 (to be discussed momentarily) to show the location of the balloon in the vasculature.

The distal end of the hollow of the tubular catheter/guide wire 120 includes a plug 148 for blocking the escape of fluid introduced into the hollow at the proximal end. (The plug 148 might also be radiopaque and/or MRI detectable to further facilitate tracking.) Joined to the distal end of the catheter/guide wire 120 is a flexible, soft coil tip advantageously made of a radiopaque material such as platinum or a material which is detectable my MRI. This, of course, would allow tracking of the leading distal end of the catheter/guide wire 120 as it is threaded through a vasculature or body cavity. The soft flexibility of the coil tip 152 minimizes the chance of traumatic piercing of body tissue as the catheter/guide wire 120 is inserted into the body.

Disposed about the tubular portion of the catheter/guide wire 120 is a sleeve 156 which extends from near or at the proximal end snugly about the catheter/guide wire tubular portion to a location just before the cuts 138 (which extend through the walls of the catheter/guide wire 120) and marker 144. At that point, the sleeve 156 widens into a resilient balloon section 146 and then, just before the distal end 140 and the coil tip 152, it again narrows to fit snugly about the distal end. Advantageously, the sleeve 156 is made of a resilient, flexible material such as polyethylene or other commonly used angioplasty balloon materials suitable for dilation of clogged or partially clogged vessels. Fluid is introduced into the hollow or lumen of the catheter/guide wire 120 and then exits the cuts 138 to cause the balloon section 146 to unfold and distend or inflate.

FIG. 2 shows an alternative embodiment of a balloon catheter/guide wire made in accordance with the present invention. Here, a tubular portion of a catheter/guide

wire 200 is made up of two parts 204a and 204b which are telescopically, but fixedly, fitted together at a joint 208. Tubular part 204a comprises the longest part and illustratively is made of stainless steel, whereas the tubular part 204b comprises the distal end of the catheter/guide wire 200 and, advantageously, is made of a more flexible shape memory alloy nickel titanium.

Formed in at least the distal end of the catheter/guide wire 200 are a plurality of cuts 212 which extend entirely through the tubular sidewall. Of course, to increase flexibility of the catheter/guide wire 200, cuts could also be formed along at least portions of the rest of the length of the catheter/guide wire.

Disposed in the hollow at the distal end of the catheter/guide wire 200 is a coil 216 advantageously made of a radiopaque material such as platinum or a material which is MRI detectable. The innermost end of the coil 216a is bunched together to provide a radiographic or MRI identification of the location of a balloon section 220, to be discussed momentarily, by positioning this portion of the coil centrally within the balloon section. The outermost portion 216b of the coil 216 is stretched to provide greater flexibility and softness in the coil to limit the possibility of puncture. A block 224 is disposed in the distal end of the tubular section 204b to prevent the escape of fluid introduced into the proximal end of the catheter/guide wire 200.

Disposed about the tubular section 204b is a sleeve 228 in which all but the balloon section 220 fits snugly about the tubular section. When fluid is introduced into the proximal end of the catheter/guide wire 200, the fluid exits through the cuts 212 to fill and inflate the balloon section 220, as desired. Advantageously, the sleeve 228 and balloon section 220 are made of a polyethylene material.

A stiffening mandrel 232 is shown inserted into the hollow of the catheter/guide wire 200 at the proximal end to allow for stiffening the catheter/guide wire along the length of the catheter/guide wire occupied by the mandrel. A handle 236 is mounted on the proximal end of the stiffening mandrel 232 and includes a stop 238 to prevent the mandrel from being inserted too far into the catheter/guide wire. (Although not shown, the wire mandrel 133 of FIG. 1 could also include a stop.)

Alternatively to using angioplasty suitable balloon materials for balloon sections 146 or 220 in FIGS. 1 and 2 respectively, a balloon material suitable for occluding rather than dilating, could be provided. Such a material includes latex rubber and may be provided at a forward section of the balloon catheter/guide wires of the FIGS. so as to occlude the flow of blood upstream of the location where the angioplasty balloon sections would be utilized to perform angioplasty. In such a case, provision would be made for inflating the occluding balloon section either prior to or at the same time as the dilating section were inflated using, for example, concentric catheters, one for inflating the occluding balloon section and the other for inflating the dilating balloon section.

In the manner described above, the catheter/guide wire has been formed and adapted to serve as a balloon catheter for use, for example, as a predilation catheter in situations such as the existence of a tight stenosis. Because of the thinness of the catheter/guide wire, it is especially suitable for insertion into vasculature having tight confines. The stiffening mandrel allows for reducing the lateral flexibility of the catheter/guide wire to enhance the insertability and threading capability of the catheter/guide wire. Because of the low profile of the entire assembly, another balloon catheter could be inserted over the entire assembly for further treatment.

It is to be understood that the above-described arrangements are only illustrative of the application of the principles of the present invention. Numerous modifications and alternative arrangements may be devised by those skilled in the art without departing from the spirit and scope of the present invention and the appended claims are intended to cover such modifications and arrangements.

CLAIMS

What is claimed is:

1. A balloon catheter/guide wire apparatus comprising

an elongate tubular body having a proximal end, a distal end, and sidewalls which define a lumen, with cuts being formed in the sidewall along at least a portion of the tubular body, including a section near the distal end, said cuts at said section extending through the sidewall to allow escape of fluid from the lumen through the cuts to the exterior, and

balloon means surrounding said section of the tubular body for inflating and expanding when fluid is introduced into the lumen at the proximal end of the tubular body, to thereby contact interior walls of a vasculature passageway into which the tubular body and balloon means are introduced.

2. Apparatus as in Claim 1 further including a radiopaque element disposed about said section of the tubular body.

3. Apparatus as in Claim 1 further including an MRI detectable element disposed about said section of the tubular body.

4. Apparatus as in Claim 1 further including an occluding tip element disposed over the distal end of the tubular body to prevent the escape of fluid therefrom.

5. Apparatus as in Claim 4 wherein said occluding tip element comprises a flexible coil.

6. Apparatus as in Claim 1 wherein said tubular body is comprised of nickel-titanium alloy.

7. Apparatus as in Claim 1 wherein said balloon means comprises an elongate sleeve disposed about the tubular body, said sleeve including an expandable resilient section disposed about said section of the tubular body to inflate and expand when fluid is introduced into the lumen at the proximal end of the tubular body.

8. Apparatus as in Claim 1 wherein at least the proximal end of the tubular body is comprised of stainless steel.

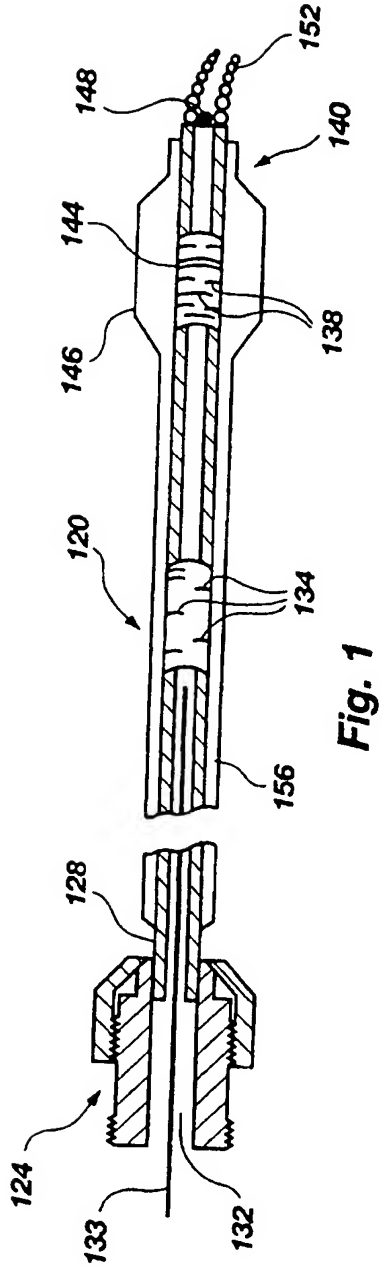
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Fig. 1

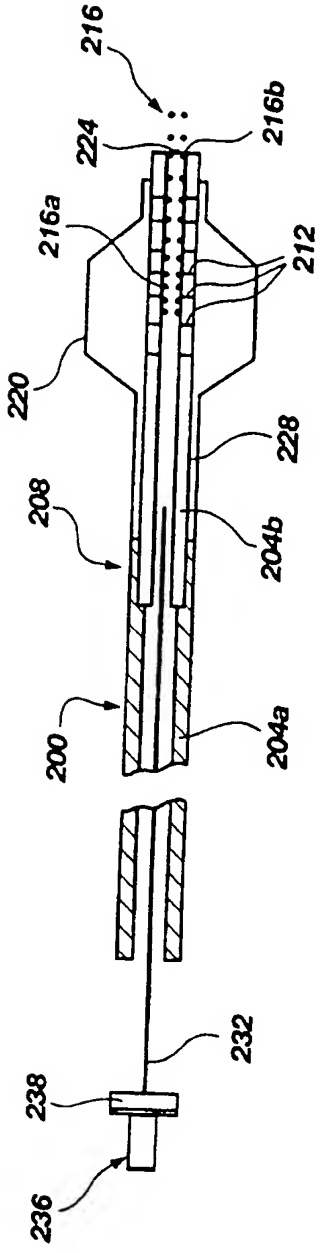
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Fig. 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/08640

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 29/00
US CL :604/96

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/95-103; 606/192, 194

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS (CATHETER, MRI)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,998,923 A (SAMSON et al.) 12 March 1991, Abstract.	1, 2, 4-8
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Y		3
Y	US 5,387,235 A (CHUTER) 07 February 1995, Abstract.	3

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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